



## Personal Protective Equipment

The health care workers who are on the frontlines of responding to the coronavirus disease (COVID-19) outbreak are currently grappling with severe shortages of personal protective equipment (PPE). Such equipment includes eye protection, isolation gowns, facemasks, and N95 respirators. These products are critical to protecting the individuals caring for, testing, and screening patients with COVID-19. Many providers have taken proactive steps themselves to procure more supplies, taking to social media seeking donations of PPE. [Politico](#) and other news outlets are currently tracking hospital capacity, patient surge, and providers' ability to obtain PPE, and collecting stories about how COVID-19 is impacting providers' own health.

### Public Health Emergency Determination and Personal Respiratory Device EUA

On February 4, 2020, U.S. Department of Health and Human Services Secretary Alex Azar [determined](#) that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the HHS Secretary [declared](#) on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak. Health care personnel can access a list of authorized respirators [here](#).

### PREP Act Declaration

On March 10, 2020, Secretary Azar took further action by issuing a [declaration](#) pursuant to the Public Readiness and Emergency Preparedness (PREP) Act, which authorizes the Secretary to provide liability immunity for activities related to medical countermeasures against COVID-19.

### DPA Invocation

On March 18, 2020, President Trump [invoked](#) the Defense Production Act (DPA), which allows the federal government to compel companies through loans, loan guarantees, purchases and purchase commitments to prioritize and expedite the manufacture of medical supplies that are in short supply. The President delegated the key authority for implementing the DPA to Secretary Azar.

Separately, General Motors Co. Chief Executive Officer Mary Barra offered to manufacture hospital ventilators in auto factories closed because of the coronavirus outbreak, according to top White House economic adviser Larry Kudlow.

### FDA Recommendations Regarding Gowns and Surgical Masks

On March 11, 2020, the Food and Drug Administration (FDA) issued a [letter](#) to health care providers intended to aid in the management of gowns and surgical masks. The letter outlines recommended conservation strategies for use by health care organizations and personnel. For surgical masks and gowns, the FDA recommends that health care providers follow these strategies based on the supply needs of their health care organization. Gowns that are ANSI/AAMI PB70 Level 1 and 2 barrier protection are considered non-surgical isolation gowns. Gowns that have ANSI/AAMI PB70 Level 3 and 4 barrier protection and/or can be used for a sterile procedure are considered surgical gowns or surgical isolation gowns.

## Conventional Capacity Strategies

supply levels are adequate to provide patient care without any change in routine practice

- Use FDA-cleared surgical masks and gowns according to labeling and local, state, and federal requirements.
- Employ [engineering and administrative controls](#) following Centers for Disease Control and Prevention (CDC) and Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines to reduce the need for surgical masks while minimizing risks to health care providers and patients.
- Specifically, for gowns, consider:
  - Implementing the use of [reusable gowns](#) instead of disposable single use gowns.
  - Using ANSI/AAMI PB70 standard Level 3 or 4 gown for surgery/invasive procedures with a medium to high risk of contamination.
  - Using ANSI/AAMI PB70 standard Level 1 or 2 gown for surgery/invasive procedures with a low risk of contamination.
  - Using non-surgical isolation gowns for routine care of patients that are suspected to be infected with COVID-19.

## Contingency Capacity Strategies

limited supply levels may change patient care, but may not have a significant impact on patient care and health care provider safety

- During times of limited access to surgical masks, facilities could consider having health care providers continue to wear the same surgical mask, remove only used gloves and gowns, and perform hand hygiene between treating patients with the same infectious disease diagnosis or exposure who are maintained in a confined area. If the mask, gloves, or gowns become contaminated, replace them.
- For training, use gowns that are beyond the manufacturer-designated shelf life, if available.
- Prioritize the use of gowns and surgical masks by the type of activities required for patients. If there are shortages of gowns, they should be prioritized for aerosol-generating procedures, care activities where splashes and sprays are anticipated, and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of health care providers.

## Crisis or Alternate Strategies

may need to be considered if surgical mask or gown demand exceeds the supply

- If Surgical Masks and/or Gowns Are Running Low
  - Extend the use of single use gowns for health care providers without changing the gown between patients with the same infectious disease diagnosis or exposure who are maintained in a confined area. If the gown becomes contaminated, replace it.
  - Use surgical masks and/or gowns that meet CDC recommendations and/or ANSI standards for fluid resistance and bacterial filtration efficiency.
  - Prioritize the use of unexpired FDA-cleared surgical masks for health care providers in procedures where it is important to protect the health care provider and/or the patient from risk of exposure to blood and body fluids.
  - Use surgical masks beyond the manufacturer-designated shelf life in a setting where there is a lower risk of transmission. The user should visibly inspect the product prior to use and, if there are concerns, discard the product.

- Re-use surgical masks during care for multiple patients where they are used to protect the health care provider from an activity with low transmission risk and thus do not create a risk to the health care provider or patient. If the mask becomes contaminated, replace it.
- Be aware that counterfeit masks and gowns may be on the market, especially during this time of reduced supply.
- If No Surgical Masks and/or Gowns Are Available, see [CDC's Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood and Body Fluids](#)
  - The [National Institute for Occupational Safety and Health](#) (NIOSH) and the [Occupational Safety and Health Administration](#) (OSHA) have issued standards and recommendations for protective clothing based on fluid barrier properties.

The FDA notes that it is collaborating with manufacturers of surgical masks and gowns to better understand the current supply chain issues related to the COVID-19 outbreak, and to avoid any widespread shortages of these products. According to an [FAQ](#) issued by the FDA on shortages of surgical masks and gowns, the agency is also collaborating with manufacturers of PPE to help facilitate mitigation strategies related to the COVID-19 outbreak. Medical device manufacturers are not required to notify the FDA when they become aware of a circumstance that could lead to a device shortage or meaningful disruption in the supply of that device in the United States.

For potential or actual supply issues, email information to the FDA at [deviceshortages@fda.hhs.gov](mailto:deviceshortages@fda.hhs.gov). Anyone – user, patient, manufacturer, or organization within the supply chain – who is aware of a delay in distribution of a product, and/or anticipates a potential or actual shortage, can notify the agency.

## FDA Recommendations Regarding Gloves

On March 20, 2020, the Food and Drug Administration (FDA) issued a [letter](#) to health care providers intended to aid in the management of surgeons' gloves and patient examination gloves. The following conservation strategies for use by health care organizations and personnel are categorized for a range of needs and supply levels and are intended to assist health care organizations as they determine procedures during the COVID-19 pandemic. The FDA issued [frequently asked questions \(FAQ\) on shortages of medical gloves](#).

The conservation strategies described below are intended to augment, and not intended to replace, specific controls and procedures developed by health care organizations, the [Centers for Disease Control and Prevention](#) (CDC), or the CDC's [Healthcare Infection Control Practices Advisory Committee](#) (HICPAC) to aid in infection prevention and control. These strategies are not limited to use in the care of patients infected with COVID-19. Health care organizations may find additional useful information in guidelines on modifications to medical standards of care during a crisis.

## Conservation Strategies

For **medical gloves**, health care providers may wish to consider these strategies and risk mitigations based on the supply needs of their health care organization.

**Conventional Capacity Strategies** (supply levels are adequate to provide patient care without any change in routine practice)

- Nonsterile disposable patient examination gloves, which are used for routine patient care in health care settings, are appropriate for the care of patients with suspected or confirmed COVID-19.
- Use FDA-cleared medical gloves according to labeling and local, state, and federal requirements.
- Employ [engineering and administrative controls](#) following the CDC's and HICPAC guidelines to reduce the need for medical gloves while minimizing risks to health care providers and patients. Some of the CDC's [Strategies for Optimizing the Supply of N95 Respirators](#) may also be useful for gloves conservation.

- Reserve use of sterile gloves for procedures in which sterility is required.

## Contingency Capacity Strategies

limited supply levels may change patient care, but may not have a significant impact on patient care and health care provider safety

- For training or demonstration in which broad barrier protection is not needed, use gloves that are beyond the manufacturer-designated shelf life, if available.

## Crisis or Alternate Strategies if Medical Gloves are Running Low or Not Available

may need to be considered if medical glove supplies are critically low and demand is high

- Refer to the CDC's [Hand Hygiene in Healthcare Settings](#)
- Use medical gloves beyond the manufacturer-designated shelf life in a setting where there is a lower risk of transmission (for example, non-surgical, non-sterile). The user should visibly inspect the gloves prior to use and, if there are concerns (for example, discolored or visible tears, holes), discard the gloves.
- Extend the use of medical gloves for health care providers without changing the gloves between patients with the same infectious disease diagnosis or exposure and no other infections. Gloved hands can be cleaned between patients and at other times when hand hygiene would normally be performed during routine patient care. Alcohol-based hand sanitizers may degrade vinyl gloves. If a glove becomes damaged (for example, discolored, deteriorated, visible tears, holes) or contaminated (for example, body fluids, chemotherapy drugs), replace it.
- Consider using radiographic protective gloves or radiation attenuating surgeon's gloves that are clean and offer fluid barrier protection. These gloves cannot be sterilized but can be cleaned following the manufacturer's labeling.
- Consider using non-medical gloves such as those used for food service, embalming, cleaning, or other industrial-grade gloves that most closely align with the ASTM standards for medical gloves as outlined in the FDA's [Medical Glove Guidance Manual](#).
- **Be aware that counterfeit medical and non-medical gloves may be on the market, especially during this time of reduced supply.**

## CDC COVID-19 Interim Infection Prevention and Control Recommendations

The CDC has issued [guidance](#) for health care personnel caring for patients with confirmed or possible COVID-19 infection. Based on the current COVID-19 situation and availability of PPE, CDC has issued specific recommendations. CDC instructs health care personnel to adhere to [Standard, Contact, and Airborne](#) Precautions when caring for patients with COVID-19 infection. These precautions include the use of PPE.

### PPE Availability

CDC communicates regularly with health care industry partners, as well as PPE manufacturers and distributors, to assess availability of PPE. Given decreases in exports from select countries and increases in demand due to the global outbreak, manufacturers of select types of PPE are reporting increased volume of orders and challenges in meeting order demands. Specific challenges are being reported for N95 respirators and facemasks. Orders received are up to 10-fold normal demand for these items. The CDC states that plans for surge manufacturing globally are underway.

Distributors of select types of PPE are also reporting an increased volume of orders from customers and challenges in meeting order demands for PPE, specifically for N95 respirators and facemasks. Due to decreased exports from overseas by manufacturers, distributors are reporting that these items are being placed on allocation, and orders are being filled based on historical demands for existing customers. At present, shortfalls may be anticipated to continue for the next 3–4 months.

The CDC has stated that U.S. health care systems are reporting higher than normal use for N95 respirators, due to fit testing and stockpiling, to prepare for possible widespread COVID-19 transmission. Orders are being placed in higher volumes to meet these needs. Some health care systems have begun reporting that orders for N95 respirators and facemasks are not being filled or are only being partially filled by distributors. In addition, major pharmacy chains have reported stock outs of N95 respirators and facemasks with delays in replenishment of inventory.

CDC is encouraging health care systems to implement the following [strategies](#) to conserve supplies.

## Strategies for Optimizing the Supply of Eye Protection

### Conventional Capacity Strategies

- Use eye protection according to product labeling and local, state, and federal requirements.

### Contingency Capacity Strategies

- Selectively cancel elective and non-urgent procedures and appointments for which eye protection is typically used by health care personnel (HCP).
- Shift eye protection supplies from disposable to re-usable devices.
  - Consider preferential use of powered air purifying respirators (PAPRs) or full-face elastomeric respirators which have built-in eye protection.
  - Ensure appropriate cleaning and disinfection between users if goggles or reusable face shields are used.
- Implement extended use of eye protection.
  - Eye protection should be removed and reprocessed if it becomes visibly soiled or difficult to see through.
  - Eye protection should be discarded if damaged.
  - HCP should take care not to touch their eye protection. If they touch or adjust their eye protection they must immediately perform hand hygiene.
  - HCP should leave patient care area if they need to remove their eye protection. See protocol for removing and reprocessing eye protection below.

### Crisis Capacity Strategies

- Cancel all elective and non-urgent procedures and appointments for which eye protection is typically used by HCP.
- Use eye protection devices beyond the manufacturer-designated shelf life during patient care activities.
- Prioritize eye protection for selected activities such as:
  - During care activities where splashes and sprays are anticipated, which typically includes aerosol generating procedures.
  - During activities where prolonged face-to-face or close contact with a potentially infectious patient is unavoidable.
- Consider using safety glasses that have extensions to cover the side of the eyes.

- Exclude HCP at higher risk for severe illness from COVID-19 from contact with known or suspected COVID-19 patients.
  - During severe resource limitations, consider excluding HCP who may be at higher risk for severe illness from COVID-19, such as those of older age, those with chronic medical conditions, or those who may be pregnant, from caring for patients with confirmed or suspected COVID-19 infection.
- Designate convalescent HCP for provision of care to known or suspected COVID-19 patients.
  - It may be possible to designate HCP who have clinically recovered from COVID-19 to preferentially provide care for additional patients with COVID-19. Individuals who have recovered from COVID-19 infection may have developed some protective immunity, but this has not yet been confirmed.

### Selected Options for Reprocessing Eye Protection

- Adhere to recommended manufacturer instructions for cleaning and disinfection.
- When manufacturer instructions for cleaning and disinfection are unavailable, such as for single use disposable face shields, consider:
  - While wearing gloves, carefully wipe the inside, followed by the outside of the face shield or goggles using a clean cloth saturated with neutral detergent solution or cleaner wipe.
  - Carefully wipe the outside of the face shield or goggles using a wipe or clean cloth saturated with Environmental Protection Agency (EPA)-registered hospital disinfectant solution.
  - Wipe the outside of face shield or goggles with clean water or alcohol to remove residue.
  - Fully dry (air dry or use clean absorbent towels).
  - Remove gloves and perform hand hygiene.

### Strategies for Optimizing the Supply of Isolation Gowns

#### Conventional Capacity Strategies

- Use isolation gown alternatives that offer equivalent or higher protection.

#### Contingency Capacity Strategies

- Selectively cancel elective and non-urgent procedures and appointments for which a gown is typically used by HCP.
- Shift gown use towards cloth isolation gowns.
  - Laundry operations and personnel may need to be augmented to facilitate additional washing loads and cycles.
  - Systems are established to routinely inspect, maintain, and replace reusable gowns when needed.
- Consider the use of coveralls.
- Use of expired gowns beyond the manufacturer-designated shelf life for training.
- Use gowns or coveralls conforming to international standards.

#### Crisis Capacity Strategies

- Cancel all elective and non-urgent procedures and appointments for which a gown is typically used by HCP.
- Extended use of isolation gowns.
- Re-use of cloth isolation gowns.
- Prioritize gowns. Gowns should be prioritized for the following activities:
  - During care activities where splashes and sprays are anticipated, which typically includes aerosol generating procedures

- During the following high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of healthcare providers

### When No Gowns Are Available

- Consider using gown alternatives that have not been evaluated as effective.
  - Disposable laboratory coats
  - Reusable (washable) patient gowns
  - Reusable (washable) laboratory coats
  - Disposable aprons
  - Combinations of clothing:

### Strategies for Optimizing the Supply of Face Masks

#### Conventional Capacity Strategies

Use facemasks according to product labeling and local, state, and federal requirements.

- FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are anticipated, including surgical procedures.
- Facemasks that are not regulated by FDA, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays.

#### Contingency Capacity Strategies

- Selectively cancel elective and non-urgent procedures and appointments for which a facemask is typically used by HCP.
- Remove facemasks for visitors in public areas.
- Implement extended use of facemasks.
  - The facemask should be removed and discarded if soiled, damaged, or hard to breathe through.
  - HCP must take care not to touch their facemask. If they touch or adjust their facemask they must immediately perform hand hygiene.
  - HCP should leave the patient care area if they need to remove the facemask.
- Restrict facemasks to use by HCP, rather than patients for source control.

#### Crisis Capacity Strategies

- Cancel all elective and non-urgent procedures and appointments for which a facemask is typically used by HCP.
- Use facemasks beyond the manufacturer-designated shelf life during patient care activities.
- Implement limited re-use of facemasks.
  - The facemask should be removed and discarded if soiled, damaged, or hard to breathe through.
  - Not all facemasks can be re-used.
  - HCP should leave patient care area if they need to remove the facemask. Facemasks should be carefully folded so that the outer surface is held inward and against itself to reduce contact with the outer surface during storage. The folded mask can be stored between uses in a clean sealable paper bag or breathable container.
- Prioritize facemasks for selected activities such as:
  - For provision of essential surgeries and procedures
  - During care activities where splashes and sprays are anticipated
  - During activities where prolonged face-to-face or close contact with a potentially infectious patient is unavoidable



- For performing aerosol generating procedures, if respirators are no longer available

### When No Facemasks Are Available, Options Include

- Exclude HCP at higher risk for severe illness from COVID-19 from contact with known or suspected COVID-19 patients.
- Designate convalescent HCP for provision of care to known or suspected COVID-19 patients.
- Use a face shield that covers the entire front (that extends to the chin or below) and sides of the face with no facemask.
- Consider use of expedient patient isolation rooms for risk reduction.
- Consider use of ventilated headboards.
- HCP use of homemade masks.

### Strategies for Optimizing the Supply of N95 Respirators

#### Conventional Capacity Strategies

- Engineering controls reduce exposures for HCP by placing a barrier between the hazard and the HCP. Engineering controls can be very effective as part of a suite of strategies to protect HCP without placing primary responsibility of implementation on them.
  - Isolation in airborne infection isolation room
  - Use of physical barriers
  - Properly maintained ventilation systems
- Administrative controls are employer-dictated work practices and policies that reduce or prevent hazardous exposures. Their effectiveness depends on employer commitment and HCP acceptance and consistent use of the strategies. Regular training, monitoring and reinforcement are necessary to ensure that policies and procedures are followed consistently. Many of these strategies should already be incorporated into existing infection prevention and control policies in healthcare settings.
  - Limit number of patients going to hospital or outpatient settings
  - Exclude all HCP not directly involved in patient care
  - Limit face-to-face HCP encounters with patient
  - Exclude visitors to patients with known or suspected COVID-19
  - Source control
  - Cohorting patients
  - Cohorting HCP
  - Telemedicine
  - Training on indications for use of N95 respirators
  - Training on use of N95 respirators
  - Just in time fit testing
  - Limiting respirators during training
  - Qualitative fit testing
- PPE and Respiratory Protection
  - Surgical N95 respirators
  - Use of alternatives to N95 respirators

#### Contingency Capacity Strategies

- Administrative Controls
  - Decrease length of hospital stay for medically stable patients with COVID-19.
- PPE and Respiratory Protection



- Use of N95 respirators beyond the manufacturer-designated shelf life for training and fit testing.
- Extended use of N95 respirators.
- Limited re-use of N95 respirators for tuberculosis.

### Crisis Capacity Strategies

- PPE and Respiratory Protection
  - Use of respirators beyond the manufacturer-designated shelf life for health care delivery.
  - Use of respirators approved under standards used in other countries that are similar to NIOSH-approved N95 respirators.
  - Limited re-use of N95 respirators for COVID-19 patients.
  - Use of additional respirators beyond the manufacturer-designated shelf life for health care delivery.
  - Prioritize the use of N95 respirators and facemasks by activity type.

### When No Respirators are Left

- Administrative Controls
  - Exclude HCP at higher risk for severe illness from COVID-19 from contact with known or suspected COVID-19 patients.
  - Designate convalescent HCP for provision of care to known or suspected COVID-19 patients.
- Engineering Controls
  - Expedient patient isolation rooms for risk-reduction
  - Ventilated headboards
- PPE and Respiratory Protection
  - HCP use of non-NIOSH approved masks or homemade masks.

In addition to the CDC's Interim Infection Prevention and Control Recommendations for COVID-10, the agency has issued and [FAQ on Infection Control](#) and an [FAQ About PPE](#).